

REQUEST FOR PERSONAL INTERVIEW

At the outset, Applicants' undersigned attorney hereby requests that the Examiner, in the event the instant Amendment does not place this case in condition for allowance, telephone the undersigned in order to schedule a personal interview^{1/}.

THE REJECTION

Claims 9, 10 and 12 are rejected under 35 U.S.C 102(b) as being anticipated by Edwards, Jr. (U.S. Patent No. 5,316,770). The Examiner states the bases of rejection are for the reasons of record and also, points out reasons that Edwards is very clear in stating that feed containing phytase can be administered to animals such as "cattle", see col. 6, lines 40. The Examiner further states that if one administers the phytase to cattle to prevent tibial dyschondroplasia (in conformity with Edwards) then one would also, inherently, treat or prevent the cattle's mastitis.

This rejection is respectfully traversed. Applicants' Claims 9, 10 and 12 have been presented, as noted, to utilize language reciting that the animal is a "dairy cow" and thus the claims are directed to a method for preventing mastitis by administering a therapeutic amount of phytase to the dairy cows. Edward at best suggests administering phytase to animals such as "cattle", but does not disclose or teach administering a feed composition containing phytase to a dairy cow. Accordingly, there is no *prima facie* case of anticipation.

Moreover, despite the boiler plate recitation of disparate animals at column 6, lines 34-45, those of ordinary skill also recognize that Edwards simply does not actually suggest administering phytase to prevent tibial dyschondroplasia in cattle, let alone in dairy

^{1/} This amendment must be entered since the subject matter of the amendment was previously before the Examiner in now-cancelled claim 11. That is, the Amendment cannot, as a matter of fact, require further consideration or search.

cows. In this regard, those of ordinary skill appreciate that the laundry list of animals recited by Edwards makes no sense technically.

It is very well-understood that tibial dysclondroplasia, also known as Ollier's disease, is a disorder affecting the growth plate in which the hypertrophic cartilage is not resorbed and ossified in a normal fashion, resulting in masses of cartilage with disorderly arrangement of chondrocytes showing variable proliferative and hypertrophic changes.

At the outset, despite Edwards' specifically mentioning cattle, there is no basis in fact to administer phytase to "cattle" to prevent tibial dysclondroplasia, since no case of that disease in cattle has been uncovered. Cattle simply do not grow quickly enough to engender growth plate disorders. Moreover, even if such a case has been known but not reported in the literature, such would be found at best in either (i) beef or (ii) very young cattle (which grow the fastest), and not dairy cows (which are not at all subjected to rapid growth) as recited in the pending claims. In this regard, the prior art must not be read in a manner that represents a less sophisticated approach that is not worthy of one of ordinary skill. In re Gurley, 31 USPQ2d 1130 (Fed. Cir. 1994).

Claims 1-3, and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards, Jr. in view of WO 93/16175, Bedford et al., Lyons and CN 1135297.

As noted above, Edwards teaches administering phytase to animals and mentions "cattle". However, Edward does not teach or suggest to those of ordinary skill administering phytase to dairy cows to prevent tibial dyschondroplasia (since doing so makes no sense) and accordingly, cannot even inherently teach preventing mastitis in dairy cows. Rather, although Edwards mentions cattle, the reference is particularly directed towards treatment of fowl.

Nor, in any event can there be any basis in fact for combining Edwards with the secondary references since there is plainly no relationship between (i) hypertrophic cartilage resorption disorder and (ii) mastitis, which is an inflammation of the udder typically caused by infection.

WO 93/16175 merely discloses "feed preparation for monogastric animals", and contains no disclosure of administering of phytase to a dairy cow.^{2/}

Bedford teaches the administration of a feed comprising enzymes to animals such as cattle. Bedford teaches "an enzyme feed additive comprising a xylanase, a protease and optionally a β -glucanase". At column 8, lines 16-19, Bedford provides a list of other enzymes that may be included. Phytase is mentioned in that list, but there is no disclosure relating to (i) administration of phytase to prevent mastitis nor of (ii) administering phytase to dairy cows, let alone administering phytase to treat or prevent mastitis in dairy cows.

Lyons teaches that phytase is used in animal feed and that zinc is commonly used in feeds to treat mastitis. However, Lyons does not teach or suggest a process of preventing mastitis in dairy cows by administering feed containing phytase.

CN 1135297 is directed to a "Feed additive for bull-frog cultivation containing zinc methionine sulphate". The document relates to feed for frogs and contains no disclosure related to the administration of phytase to mammals.

The Examiner states that Edwards clearly provides the teaching for one of ordinary skill in the art to use the phytase for the prevention of tibial dyschondroplasia in cattle and in doing so one would also be treating the cattle's mastitis.

However, tibial dyschondroplasia and mastitis are completely different diseases, and causes therefor are also different. Tibial dyschondroplasia is indicated by genetic factors and rapid growth. Edwards describes that "tibial dyschondroplasia is a

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Obviously, cows are ruminants, which are not monogastric.

skeletal abnormality which occurs in rapidly growing animals such as broiler chickens or turkeys" (col. 1, lines 65-68). In contrast, mastitis is caused by bacterial infection and completely different from tibial dyschondroplasia. Mastitis is inflammation of the breast or udder usually caused by infection. The microorganisms relating to the cause of mastitis of mammals are *Streptococcus agalactiae*, *Staphylococcus aureus*, *Escherichia coli*, *Mycobacterium tuberculosis*, *Bacillus cereus*, *Pseudomonas pyocyaneus*, etc. Thus, while efficacy for the prevention of tibial dyschondroplasia is observed in poultry, no one skilled in the art could reasonably expect any efficacy for the treatment of mastitis, let alone in dairy cows.

Accordingly, it would plainly not have been obvious to those of ordinary skill in the art to combine these references to produce the present invention.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-3, 7-10, 12 and 13 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lawrence S. Perry", with a long horizontal flourish extending to the right.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

9. (Amended) A method for preventing mastitis in [female ruminants] dairy cows, which comprises administering feedstuff comprising a therapeutically effective amount of phytase to lactating [ruminants] dairy cows.

10. (Amended) The method for preventing mastitis in [ruminants] dairy cows of claim 9, which comprises administering feedstuff containing 50 to 5,000 units phytase per kg of dry feed matter.

11. (Canceled)

12. (Amended) The [methods] method for preventing mastitis in [ruminants] dairy cows of claim 10, wherein the feedstuff comprises formula feed.

13. (Amended) The method for preventing mastitis in [ruminants] dairy cows of claim 10, wherein the feedstuff comprises zinc methionine sulfate.

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